Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation—Part 3. Licensing of Sources of Radiation.

28-35-181o. Specific licenses to manufacture and distribute sources and devices for use as a calibration, transmission, or reference source or for certain medical uses.

(a) Each application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed as specified in K.A.R. 28-35-181d for use as a calibration, transmission, or reference source or for one or more of the uses listed in 10 C.F.R. 35.400, 35.500, 35.600, and 35.1000, as adopted by reference in K.A.R. 28-35-264, shall include the following information regarding each type of source or device:

(1) The radioactive material contained, its chemical and physical form, and amount;

(2) details of design and construction of the source or device;

(3) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and in accidents;

(4) for devices containing radioactive material, the radiation profile for a prototype device;

(5) details of quality control procedures to ensure that the production sources and devices meet the standards of the design and prototype tests;

(6) procedures and standards for calibrating sources and devices;

(7) legend and methods for labeling sources and devices as to their radioactive content;

(8) radiation safety instructions for handling and storing the source or device. These instructions shall be included on a durable label attached to the source or device. However, instructions that are too lengthy for the label may be summarized on the label and printed in detail on a brochure that is referenced on the label;

(9) the label that is to be affixed to the source or device or to the permanent storage container for the source or device. The label shall contain information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the department for distribution to persons licensed under K.A.R. 28-35-181d or under an equivalent license of the nuclear regulatory commission (NRC) or an agreement state. Labeling for sources that do not require long-term storage may be on a leaflet or brochure that is to accompany the source; and

(10) documentation that the source or device is listed on the nuclear regulatory commission's sealed source and device registry.

(b)(1) If the applicant wants to have the source or device required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device, or similar sources or devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval between tests for leakage of radioactive material, information that includes the following shall be considered by the secretary:

(A) The nature of the primary containment;

(B) the method for protection of the primary containment;

(C) the method of sealing the containment;

(D) containment construction materials;

(E) the form of the contained radioactive material;

(F) the maximum temperature withstood during prototype tests;

(G) the maximum pressure withstood during prototype tests;

(H) the maximum quantity of contained radioactive material;

(I) the radiotoxicity of contained radioactive material; and

(J) the applicant's operating experience with identical sources or devices or with similarly designed and constructed sources or devices.

(Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended July 27, 2007; amended March 18, 2011; amended May 4, 2018.)

***** Authenticated Kansas Administrative Regulation *****